

## REMARKS

This paper is filed in accompaniment to a Request for Continued Examination. A Notice of Appeal was filed February 12, 2004. This Request for Continued Examination is due on August 12, 2004, by virtue of the attached petition and fee for a four-month extension of time to respond. Applicants respectfully request that the claims be reconsidered for allowance in view of the following remarks.

### **I. Status of the Claims**

Claims 34-60 are pending in the instant application and stand rejected under 35 U.S.C. §101/112 first paragraph for lack of utility/enablement. Applicants respectfully traverse the rejections because as explained in further detail herein below, the rejections articulate a position contrary to that articulated in the USPTO Examination Guidelines for Utility Rejections and in view of the recognition in the art of the utility asserted by the Applicants.

### **II. Rejection under 35 U.S.C. §101/§112 should be withdrawn**

Briefly reiterating the rejection, in the Final Office Action dated August 12, 2003, the Examiner maintained the rejection of claims 34-60 under 35 U.S.C. §101 for lack of utility and further indicated that as the claims were rejected for lack of utility under 35 U.S.C. §101, a rejection under §112, first paragraph for lack of enablement also was appropriate. More particularly, it was the Examiner's position that "disclosing that the claimed nucleic acid encodes a protein that is similar in sequence and general structure to IL-1 receptor (IL-1R) does not impart a utility common to all members of this family, because the specific activity and physiological role of the claimed nucleic acid." Office Action, page 3, second paragraph. Applicants traverse the rejection because the Examiner's position is in direct contradiction to the position posited by the United States Patent Office (USPTO).

Applicants have sought guidance in the USPTO Revised Interim Utility Guidelines (downloaded from USPTO website: <http://www.uspto.gov/web/menu/utility.pdf>,

and referred to hereafter as "Guidelines"). For the Examiner's convenience, Applicants attach hereto a copy of the complete set of these Guidelines as downloaded (Appendix A). Applicants specifically refer to Example 10 of these Guidelines as it provides a fact pattern most analogous to the situation at hand. The fact pattern in Example 10 is as follows:

"The specification discloses that a cDNA library was prepared from human kidney epithelial cells and 5000 members of this library were sequenced and open reading frames were identified. The specification discloses a Table that indicates that one member of the library having SEQ ID NO: 2 has a high level of homology to a DNA ligase. The specification teaches that this complete ORF (SEQ ID NO: 2) encodes SEQ ID NO: 3. An alignment of SEQ ID NO: 3 with known amino acid sequences of DNA ligases indicates that there is a high level of sequence conservation between the various known ligases. The overall level of sequence similarity between SEQ ID NO: 3 and the consensus sequence of the known DNA ligases that are presented in the specification reveals a similarity score of 95%. A search of the prior art confirms that SEQ ID NO: 2 has high homology to DNA Ligase encoding nucleic acids and that the next highest level of homology is to alpha-actin. However, the latter homology is only 50%. Based on the sequence homologies, the specification asserts that SEQ ID NO: 2 encodes a DNA ligase."

The claim that is provided in Example 10 is to "An isolated and purified nucleic acid comprising SEQ ID NO: 2." In the analysis of this claim for utility, the Guidelines state:

"Based upon applicant's disclosure and the results of the PTO search, *there is no reason to doubt the assertion* that SEQ ID NO: 2 encodes a DNA ligase. Further, DNA ligases have a well-

established use in the molecular biology art based on this class of protein's ability to ligate DNA. *Consequently the answer to the question is yes. . . . Thus, the conclusion reached from this analysis is that a 35 U.S.C. §101 rejection and a 35 U.S.C. § 112, first paragraph, utility rejection should not be made."*

The fact pattern in the instant application is directly analogous to the fact pattern of Example 10 of the Guidelines. Disclosed in the instant specification is a sequence, SEQ ID NO:1 (see page 8-9), it is identified as having sequence homology with IL-1R (see page 9). This asserted utility is credible, specific and substantial. IL-1R proteins were known in the art at the time the application was filed. Applicants submit that the disclosure as filed provides a *prima facie* assertion of credible utility and the statements made by the examiner are unsupported by evidence to the contrary. In the absence of such evidence the utility rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, should be withdrawn.

In addition to the fact that the USPTO Guidelines themselves mandate that the articulated rejection under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph should be withdrawn, there are numerous post-filing references that corroborate that the utility of SIGIRR as an IL-1R receptor is a credible, substantial and specific utility. Attached hereto in Appendix B is a Nature Immunology paper authored by Wald et al. entitled "SIGIRR, a negative regulator of Toll-like receptor -interleukin 1 receptor signaling" (Nature Immunology, 4(9):920-927, 2003). This paper expressly confirms that SIGIRR is an interleukin 1 receptor family member (See abstract). This paper provides clear and convincing evidence that the initially asserted utility for SIGIRR was credible, substantial and specific. Numerous other post-filing references, e.g., O'Neill "SIGIRR puts brakes on Toll-like receptors" (Nature Immunology, 4(9):823-824, 2003; copy of paper attached as Appendix C), Mantovani et al., "Extracellular and intracellular decoys in the tuning of inflammatory cytokines and Toll-like receptors: the new entry TIR8/SIGIRR" (J Leukoc Biol., 75(5):738-42, 2004; copy of abstract attached as Appendix D); Polentarutti et al., "Unique pattern of expression and inhibition of IL-1 signaling by the IL-1 receptor family

member TIR8/SIGIRR" (Eur Cytokine Netw.;14(4):211-8, 2003; copy of abstract attached as Appendix E) establish that the utility asserted by the inventor in the instant application as an interleukin-1 receptor is accepted in the art and as such these references have clearly corroborated the assertion that SIGIRR is an interleukin-1 receptor. A clear example of this is found, for example, in the first line of the abstract of Polentarutti et al., which states "TIR8, also known as single Ig IL-1R-related molecule (*SIGIRR*), *is a member of the IL-1 receptor family*."

In view of the above discussion, Applicants respectfully request that the rejection of the claims under 35 U.S.C. §101/§112 should be withdrawn and the claims should be reconsidered for allowance.

### III. Conclusions

Applicants believe that all of the rejections have been overcome and the claims of the instant application are now in condition for allowance and request an early indication of such a favorable disposition of the case. The Examiner is invited to contact the undersigned with any questions, comments or suggestions relating to the referenced patent application.

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Respectfully submitted,

By 

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